SOUTH CAROLINA CENTRAL CANCER REGISTRY SCIENTIFIC REVIEW BOARD CRITERIA FORM

PRINCIPAL INVESTIGATOR:
AGENCY AFFILIATION (include address):

PHONE: FAX: EMAIL:

Co-INVESTIGATOR: AGENCY AFFILIATION:
PHONE: FAX: EMAIL:

Co-INVESTIGATOR: AGENCY AFFILIATION:
PHONE: FAX: EMAIL:

Co-INVESTIGATOR: AGENCY AFFILIATION:
PHONE: FAX: EMAIL:

TITLE OF PROJECT:

PROJECT PERIOD: from to (mm/dd/yyyy)

SPONSORING AGENCY:

SPONSORING AGENCY ASSIGNMENT NUMBER (if known):

IS THIS PROJECT CURRENTLY FUNDED? ☐ Yes ☐ No

HAS THIS PROJECT BEEN APPROVED BY AN INSTITUTIONAL REVIEW BOARD FOR HUMAN SUBJECTS? ☐ Yes ☐ No

IF YES, WHAT IRB? WHEN? (mm/dd/yyyy)

Please Answer the Following Questions

1. What data elements are requested from the SCCCR?
(CHECK ALL THAT APPLY)

UNRESTRICTED

1. Patient Age at Diagnosis in years (in days if <1 year)
2. Patient Sex
3. Patient Race/Ethnicity
4. Patient County of Residence
5. Patient Marital Status
6. Accession Year/Diagnosis Year
7. Class of Case
8. Tumor Sequence Number
9. Primary Site of Tumor and Laterality

10. Tumor Characteristics (morphology type, behavior, grade)
11. Stage of Diagnosis
12. Vital Status
13. Patient Year of Death

RESTRICTED

14. Patient Name
15. Patient Address
16. Patient Social Security Number
17. Patient Birth Date
18. Patient Medical Record Number
19. Patient Cancer Registry Accession Number (facility assigned)
20. Unique Patient Number (SCCCR assigned)
21. Patient Zip-code
22. Census Tract
23. Patient Healthcare Provider ID: attending physician, surgeon, following physician
24. Healthcare Facility ID
25. Patient Date of Death
26. __ Aggregate data (other than "<5" for 1–4 or "10" for 5–9)

2. If you are requesting any restricted data element, justify this request by providing why you cannot conduct your investigation without these data.

3. Will you contact patients in any way? ☐ Yes ☐ No

If answered YES to question 3, ANSWER THE FOLLOWING:

4. How many subjects involved?

5. Age range:

6. From what geographic region of South Carolina will the cancer cases come from?

7. What specific type of cancers are you interested in selecting?

8. How will patients be contacted?

PROJECT SUMMARY

Summary for scientific merit (use additional pages if required). *Statements such as Asee protocol@ are not acceptable*. Describe specific procedures or methods to be used addressing the identified research questions. Provide evidence that this research is needed to advance knowledge (justification).

9. Study question(s):

10. How will this study question(s) / hypothesis(es) be addressed in this study?

11. Describe the study design:

12. Describe the protocol for data collection:

13. Describe the planned statistical analysis. Include a brief description of how variables will be defined, what the independent and dependent variable will be, and what specific tests will be used.

14. Describe the significance of the planned research. How does this work add to the existing literature?

15. Briefly presented the anticipated results.

16. Attach a copy of any questionnaire, written test, or recorded abstract form to be used in the study.

17. Attach a copy of any consent form.

18. List all other institutions (hospitals, schools, health care centers, etc.) other than USC, which will serve as sites for this research project.

19. Include a grant proposal or study protocol.

INFORMED CONSENT FORM ELEMENTS

(*This checklist is included for your convenience*.)

Informed Consent Forms should include the following basic elements.

a. Evidence that the subject will be able to exercise free power of choice and no element of coercion or constraint is being permitted in the obtaining of consent to participate;
_____ Yes _____ No

b. A fair explanation of the duration of the project, procedures to be followed and their purposes, including identification of any procedures which are experimental;
_____ Yes _____ No

c. A description of any attendant discomforts and risks reasonably to be expected;
_____ Yes _____ No

d. A description of the benefits reasonably to be expected;
_____ Yes _____ No

e. A disclosure of any appropriate alternative procedures that might be advantageous for the subject;
_____ Yes _____ No (does not apply to all projects)

f. An offer to answer any inquires concerning the procedures, including a telephone number and address for the contact person;
_____ Yes _____ No

g. An instruction that the subject is free to withdraw his consent and to discontinue participation in the project at any time without prejudice to the subject;
_____ Yes _____ No

h. A statement of security of data (maintaining confidentiality), especially as it relates to specific individuals;
_____ Yes _____ No

i. A statement on availability of compensation in the event of physical injury and how to obtain more information;
_____ Yes _____ No

j. No exculpatory language through which the subject is made to waive or appear to waive any of his legal rights including any release of the institution or its agents from liability for negligence;
_____ Yes _____ No

k. An order of explanations or use of words appropriate to the level of understanding and nature of the subject;
_____ Yes _____ No

l. A place for the subject to sign and date the form;
_____ Yes _____ No

m. A heading on the form stating that it is an INFORMED CONSENT FORM;
_____ Yes _____ No

n. Prominently located on the consent form must be a statement to the effect that the subject must be provided a copy of the consent form.
_____ Yes _____ No

What procedures will be used to contact patients?

Does consenting to be a subject lead to additional costs in: tests, medical care, etc. for the subject(s)? If so, who is responsible for the costs?

In your estimation, do the procedures involve any potential risk for the subject(s) - physical, psychological, social, legal or invasion of privacy and assessment of likelihood and seriousness of such risks? (If methods of research create potential risks, describe other methods, if any, that were considered and why they will not be used.)

What is the significance of potential benefits to be gained by subjects, by persons similarly situated, or by humankind in general?

What are your procedures for safeguarding the subjects' rights with respect to the following:

- security of person;

- privacy and confidentiality (including protection of data);

- embarrassment, discomfort and harassment (i.e., would there be any stigma or repercussions from having participated)?

What ways will you disseminate results of the study to participants of the study?